

REMARKS

Prior Restriction Requirement

Claims 1-14 were withdrawn from consideration due to Applicant's election in response to a prior restriction requirement. Applicant has now cancelled these claims from the application. Applicant reserves the right to pursue these claims in one or several divisional/continuing applications.

Rejection under 35 U.S.C. § 102

Claims 15-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,205,359 (hereinafter referred to as "Boveja").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Applicant respectfully submits that Boveja does not satisfy these requirements.

Claim 15 recites:

placing an implantable pulse generator in an activated mode using an external programming device; and
sending a program-selection signal to the implantable pulse generator by the external programming device, wherein the implantable pulse generator stores at least two treatment protocol programs, each treatment protocol program being associated with at least one stimulation setting, and at least one of the programs being associated with a plurality of stimulation settings;
thereafter controlling the operation of the implantable pulse generator by the external programming device.

There is no "implantable pulse generator" in Boveja. As clearly shown in the FIGURES of Boveja (see FIGS. 1A and FIG. 12) and explicitly described in Boveja (see col.

10, lines 9-14), the pulse generating circuitry is contained within an “external stimulator 42.” The elements of the Boveja system that are implanted within the patient are merely passive elements. Specifically, an inductive element (coil 46) is implanted within the patient. The implanted inductive element receives electrical pulses by an inductive coupling to the exterior patch electrode 36. The current induced in coil 46 is conducted to electrode 52 for stimulation of the vagus nerve. Coil 46, the conductive wire, and the electrode 52 would never be considered “an implantable pulse generator” by one of ordinary skill in the art.

Thus, it is clear that Boveja does not disclose an “implantable pulse generator.” Moreover, because there is no implantable pulse generator, there is no reason to send “a program-selection signal” from “an external programming device” to the implantable pulse generator.

Therefore, Boveja does not anticipate claim 15. Claims 16-20 depend from claim 15 and, likewise, are not anticipated by Boveja.

Statement in Office Action Regarding “Intended Use”

Additionally, Applicant notes that the Office Action states that the “statements of intended use have been carefully considered but are not considered to impart any further structural or method step limitations over the prior art.”

Applicant respectfully submits that the Examiner has applied an incorrect legal standard.

It is true that a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)(emphasis added). However, the legal principle discussed in *Masham* only applies to apparatus or system claims. Any language limiting the performed of a claimed process or method (whether or not characterized as an “intended use”) must be considered in judging the patentability of the process or method. For example, it is well settled that a new use of an old apparatus can constitute a patentable method or process. *See e.g., In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).

New Claims 21-26

Applicant has added new claims 21-26. The new claims are fully supported by the original application. No new matter has been entered.

Claim 21 recites:

placing an implantable pulse generator in an activated mode using an external programming device when the implantable pulse generator is implanted within a patient and the external programming device is operated by a user, wherein the implantable pulse generator stores multiple stimulation programs with each stimulation program comprising one or several stimulation sets, wherein each stimulation set defines at least one pulse parameter and an electrode configuration comprising multiple electrode polarities;

sending a program-selection signal to the implantable pulse generator by the external programming device using wireless communications, the program-selection signal identifying a stimulation program stored in the implantable pulse generator, wherein the sending does not communicate data defining one or several stimulation sets of the selected stimulation program to the implantable pulse generator; and

in response to the program-selection signal, generating and delivering electrical pulses by the implantable pulse generator as defined by the parameters of one or several stimulation sets of the selected stimulation program.

Applicant respectfully submits that Boveja does not teach or suggest each and every limitation of claim 21.

Claim 21 recites “an implantable pulse generator” that stores “multiple stimulation programs.” In contrast, Boveja is related to a fundamentally different type of stimulation system. The actual pulse generator of Boveja is an “external stimulator.” Col. 10, lines 10-12; see also external stimulator 42 as shown in FIG. 1A.

The method of claim 21 involves activating the implantable pulse generator by an external programming device. The activation occurs when the implantable pulse generator is implanted within a patient. The method further comprises “sending a program-selection signal to the implantable pulse generator by the external programming device using wireless communications...wherein the sending does not communicate data defining one or several stimulation sets of the selected stimulation program to the implantable pulse generator.”

Because Boveja utilizes an external stimulator, Boveja does not send any data to an implanted pulse generator from an external programming device, yet alone “a program-

selection signal” in the manner recited by claim 21. There is no reason to communicate “a program-selection signal” using wireless communication in Boveja, because the external stimulator of Boveja is readily accessed by the patient.

Also, even though Boveja uses the word “program” in referring to the operation of its user interface, there are no “stimulation programs” in Boveja as defined in claim 21. Specifically, the stimulation programs as recited in claim 21 comprise one or several stimulation sets. Each stimulation set in claim 21 defines “an electrode configuration comprising multiple electrode polarities.” There are no such electrode configurations in Boveja as electrode 52 (see FIG. 5) always acts as the stimulation electrode and the “case 78” always serves as the return electrode. *See* col. 11, lines 20-21. As further seen in the programs of Boveja, there are no electrode polarities. Instead, only amplitude, frequency, and pulse width parameters are listed. *See* col. 12, line 45 - col. 13, line 13.

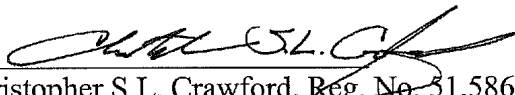
Thus, claim 21 is patentable over Boveja. Claims 22-26 depend from claim 21 and, hence, are likewise not anticipated by Boveja.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if any fee is due, please charge Deposit Account No. 50-3906, from which the undersigned is authorized to draw.

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Respectfully submitted,

By 
Christopher S.L. Crawford, Reg. No. 51,586
Advanced Neuromodulation Systems
6901 Preston Road
Plano, TX 75024
(972) 309-8006